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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/650,114      | 08/26/2003  | Erkki Heinonen       | 2532-00323          | 5885             |

26753 7590 12/13/2004

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EXAMINER

RAGONESE, ANDREA M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/650,114

Applicant(s)

HEINONEN, ERKKI

Examiner

Andrea M. Ragonese

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/8/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. **Claims 1-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Heinonen (US 6,139,506).

3. Regarding **claim 1**, Heinonen discloses an apparatus fully capable of performing a method for determining gas exchange efficiencies of volumetric portions of and the volume of the lungs of a subject to express ventilation homogeneity characteristics of volumetric portions of the lungs, said method comprising the steps of:

a. allowing the patient to breathe with breathing gases having given properties regarding the amount of an inert gas contained therein by inhaling gas from pressurized gas cylinders **22, 24** (column 4, lines 39-44)

b. ascertaining the concentration  $F_o$  of the inert gas in the lungs of the subject upon exhalation through "sampling conduit **44** connected to a device **46** for determining the concentration of one or more selected components of the gases in breathing conduit **12**" (column 4, line 55 through column 5, line 5);

c. altering the amount of the inert gas in the breathing gases provide to the subject from a pressurized tank source **48** (column 5, lines 6-16);

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- d. causing the subject to breathe breathing gases having the altered amount of inert gas through an electronically controlled valve **50** (column 5, lines 18-29);
- e. thereafter measuring the change in volume  $\Delta V_{ig}$  of the inert gas in the lungs of the subject and the concentration  $F$  of inert gas in the lungs of the subject for each breath (column 6, lines 21-28);
- f. making a determination of the lung volume  $V$  of the subject using a summation of the volume change  $\Delta V_{ig}$  of the inert gas in the lungs of the subject, the concentration  $F$  of the inert gas in the lungs of the subject, and the amount  $F_0$  of the inert gas in the breathing gases ascertained in step (b) (column 7, lines 28-41);
- g. obtaining a measure of the gas exchange efficiency of the subject's lungs using the breathing gas volume  $V_A$  of the subject and the lung volume  $V$  determined in step (f) (column 6, lines 33-38);
- h. repeating step (e) and, respectively, steps (f) and (g) for a subsequent breath of the subject to make at least one further determination of the lung volume  $V$  of the subject and obtain at least one further gas exchange efficiency measure using the data collected regarding functional residual capacity of the subject's lungs (column 6, lines 63-67);
- i. the apparatus is fully capable of forming a lung volume  $V$  data series comprising the volumes  $V$  determined for each breath and, respectively, a gas exchange efficiency data series comprising gas exchange efficiencies obtained

for each breath using the data collected regarding functional residual capacity of the subject's lungs; and

j. expressing the ventilation homogeneity of volumetric portions of the lungs of the subject by relating the series of gas exchange efficiencies to the lung volume series, just as was done to determine the functional residual capacity.

4. Regarding **claim 2**, wherein step (e) is further defined by measuring the concentration  $F$  of the inert gas in the lungs of the subject using end tidal inert gas concentrations of the subject by measuring device **46** (column 6, lines 40-46).

5. Regarding **claim 3**, wherein step (g) is further defined as obtaining a gas exchange efficiency measure comprising a dilution ratio for the amount of inert gas  $F_0$  in the breathing gases by measuring the amount of indicator gas exhaled by the subject in regards to the amount inhale by the subject.

6. Regarding **claim 4**, wherein step (j) is further defined as carrying out the expression graphically by plotting one data series on an abscissa of a graph and the other data series on an ordinate of a graph (column 9, lines 39-67).

7. Regarding **claim 5**, wherein step (h) is further defined as making a plurality of further determinations of lung volume  $V$  and as obtaining a plurality of further gas exchange efficiency measures by repeating the measurement process.

8. Regarding **claims 6-7**, further the apparatus is fully capable of performing the method by including the step (k) of normalizing the further gas exchange efficiency measure obtained in step (h) using the gas exchange efficiency measure obtained in

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step (g) for a first breath of the subject after altering the amount of inert gas in the breathing gases provided to the subject.

***Conclusion***

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Andrea M. Ragonese** whose telephone number is **571-272-4804**. The examiner can normally be reached on Monday through Friday from 8:30 am until 5:00 pm.

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMR   
December 8, 2004

  
Henry Bennett  
Supervisory Patent Examiner  
Group 3700